

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[NT007 trade name][†]
Ivermectin

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [NT007 trade name] is and what it is used for
2. What you need to know before you take [NT007 trade name]
3. How to take [NT007 trade name]
4. Possible side effects
5. How to store [NT007 trade name]
6. Contents of the pack and other information

1. What [NT007 trade name] is and what it is used for

[NT007 trade name] contains a medicine called ivermectin. It is used to treat two types of infection caused by tiny worms (filaria):

- On its own, for river blindness (onchocerciasis), an infection caused by a worm called *Onchocerca volvulus* that affects your skin, glands (lymph nodes) and eyes
- With other medicines to treat lymphatic filariasis caused by worms called *Wuchereria bancrofti*, *Brugia malayi*, or *Brugia timori*, which cause fever, cough and wheezing, swelling of the lymph nodes, swollen limbs or genitals, and kidney problems

In these infections, [NT007 trade name] kills the immature worms in your blood, which can be passed on to other people by a blood-sucking insect that bites you and then bites someone else. By killing the immature worms, [NT007 trade name] also prevents the spread of the disease in your community. However, it does not work against adult worms, so you may need to take the medicine each year, until all the worms in your body have gone.

[NT007 trade name] is also used to treat:

- an infection in your gut called intestinal strongyloidiasis. This is caused by a roundworm called *Strongyloides stercoralis*.
[NT007 trade name] may be given on its own or with another medicine as part of a community programme to deal with strongyloidiasis and other worm infections of the gut.
- skin mites (scabies). This is when tiny mites burrow under your skin and cause severe itching.
[NT007 trade name] is used in combination with other medicines for severe or crusted scabies (when

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

your skin develops thick crusts infested with many mites). It can also be given for milder scabies if direct treatment of the skin with permethrin cream or lotion has not worked or cannot be used. [NT007 trade name] may also be given to you as part of a community programme to reduce the number of infected people.

2. What you need to know before you take [NT007 trade name]

Do not take [NT007 trade name] if you are allergic to ivermectin or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your health care provider before taking [NT007 trade name].

Warnings and precautions

Talk to your health care provider before taking [NT007 trade name]. Before starting treatment with [NT007 trade name], tell your health care provider about all your medical history, including:

- if you have a weakened immune system. The medicine may not work as well if this is the case.
- if you live or have lived where there are cases of ‘eye worm’ or ‘loiasis’, an infection with a worm known as *Loa loa*. You may be at higher risk of side effects, including effects on the brain and nerves.
- if you have a symptom of river blindness (onchocerciasis) called *sowda* (itching and darkening of the skin in a part of the body such as an arm or leg). You may be at higher risk of allergic reactions affecting your skin when the medicine kills the immature worms in your body.

If any of the above apply to you (or you are not sure), talk to your health care provider before taking [NT007 trade name].

[NT007 trade name] does not kill every type of worm or parasite and only kills the immature forms of worms causing river blindness (onchocerciasis) and lymphatic filariasis. It should only be used on the advice of a health care provider.

This medicine should not be used in people who are seriously ill. Your health care provider may check your general health before you are given [NT007 trade name].

Children

[NT007 trade name] is not recommended for use in children who weigh less than 15 kg or are less than 90 cm tall.

Other medicines and [NT007 trade name]

Tell your health care provider if you are using, have recently used or might use any other medicines. In particular, tell your health care provider if you take warfarin (to prevent blood clots).

In general, you should check with your health care provider before taking any medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, tell your health care provider and ask them for advice before taking this medicine.

Pregnancy

If you are pregnant, do not take [NT007 trade name] unless your health care provider has instructed you to. It is not known if this medicine can harm the unborn baby.

Breast-feeding

[NT007 trade name] passes into breast milk in small amounts. If you are breast-feeding, ask your health care provider whether you should take this medicine. If you have just given birth, you may be asked to wait a week before taking the medicine.

Fertility

This medicine is not expected to affect fertility.

Driving and using machines

The effect of [NT007 trade name] on the ability to drive and use machines has not been studied. Some patients may get side effects such as feeling dizzy, sleepy or unsteady (a spinning sensation). If you get any of these side effects, do not drive or use machinery.

3. How to take [NT007 trade name]

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

[NT007 trade name] is available as tablets to take by mouth in a single dose. Swallow the tablets with a little clean drinking water. You can take the tablets with food or between meals.

The number of tablets to take depends on your height or weight as well as the condition you are being treated for. Your healthcare provider will tell you how many tablets you need to take.

River blindness (onchocerciasis) and lymphatic filariasis

If you are being treated as part of a community programme for river blindness or lymphatic filariasis then you will normally be given a single dose of [NT007 trade name] once a year.

The dose is usually worked out based on your *height*:

Height	Dose
90 to 119 cm	1 tablet (3 mg) as a single dose
120 to 140 cm	2 tablets (6 mg) as a single dose
141 to 159 cm	3 tablets (9 mg) as a single dose
More than 159 cm	4 tablets (12 mg) as a single dose

In some countries, this dose may be given twice a year to treat river blindness. Your health care provider will explain the details of the programme in your area.

Alternatively, for river blindness the dose is sometimes worked out based on your *weight in kg*:

Weight	Dose
15 to 25 kg	1 tablet (3 mg) as a single dose
26 to 44 kg	2 tablets (6 mg) as a single dose
45 to 64 kg	3 tablets (9 mg) as a single dose
More than 64 kg	4 tablets (12 mg) as a single dose

Small children less than 90 cm high or weighing less than 15 kg should not be given [NT007 trade name].

When used in community programmes to treat lymphatic filariasis, [NT007 trade name] is given together with other medicines. You should also read the patient leaflet for any other medicines you are given.

Intestinal strongyloidiasis and other worm infections of the gut

The recommended dose of [NT007 trade name] is a single dose based on your weight in kg:

Weight	Dose
15 to 24 kg	1 tablet (3 mg) as a single dose
25 to 35 kg	2 tablets (6 mg) as a single dose

36 to 50 kg	3 tablets (9 mg) as a single dose
51 to 65 kg	4 tablets (12 mg) as a single dose
66 to 79 kg	5 tablets (15 mg) as a single dose
More than 80 kg	6 tablets or more*

*Your health care provider will tell you how many tablets to take for the right dose

[NT007 trade name] is given on its own or with another medicine (albendazole) when used as part of community programmes to control gut worm infections. You should also read the patient leaflet for any other medicines you are given.

Scabies

The recommended dose of [NT007 trade name] is a single dose based on your weight in kg:

Weight	Dose
15 to 24 kg	1 tablet (3 mg)
25 to 35 kg	2 tablets (6 mg)
36 to 50 kg	3 tablets (9 mg)
51 to 65 kg	4 tablets (12 mg)
66 to 79 kg	5 tablets (15 mg)
More than 80 kg	6 tablets or more*

*Your health care provider will tell you how many tablets to take for the right dose

The dose is repeated once after 1 to 2 weeks.

For severe or crusted scabies, [NT007 trade name] is given to you in combination with other medicines used on the skin. Your health care provider may recommend additional doses of [NT007 trade name] if necessary, to ensure the infection is cleared. Scabies passes readily to people you come into close contact with.

Everyone who comes into contact with you, especially members of your family and partners, should visit a health care provider as soon as possible. The health care provider will decide whether these persons should also be treated for scabies. If infected contact persons are not also treated promptly, there is a danger that they could re-infect you with scabies.

You should follow hygienic measures to prevent reinfection (i.e. keeping fingernails short and clean) and clothes, towels and bedding should be thoroughly cleaned according to official recommendations, either by heat (using hot water, using a hot iron or a clothes drier) or by placing them inside sealed bags for at least a week to ensure that any remaining mites die. Your health care provider can advise you on how to do this.

If you take more [NT007 trade name] than you should

As you will normally only need a single dose of [NT007 trade name], which will be worked out by your health care provider, it is unlikely that you will take too much of the medicine. If you think you have done so, contact your health care provider straight away for advice.

If you forget to take [NT007 trade name]

If you forget to take your dose, take it as soon as you remember.

If you have any further questions on the use of this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects are usually not serious and do not last long. They are more likely to happen in people infected with several parasites. This is particularly true if they are infected with the worm *Loa loa* (eye worm, loaiasis).

The following side effects may happen with this medicine:

Allergic reactions

If you have an allergic reaction, see a health care provider straight away. The signs may include:

- sudden fever
- rapidly developing skin rash or itching; a few patients have more serious skin reactions that cause blistering or peeling, sometimes with fever and chills
- difficulty breathing

See a health care provider straight away if you notice any of the side effects above.

Other side effects

- liver problems (hepatitis)
- changes that show in some blood tests (increase of liver enzymes, increase of bilirubin in blood, increase of eosinophils)
- blood in urine

The side effects below depend on what you are taking [NT007 trade name] for. They also depend on whether you have any other infections.

People infected with **river blindness (onchocerciasis)** may have the following side effects:

- itching or rash
- joint or muscle pains
- fever
- nausea (feeling sick) or vomiting
- swelling of lymph nodes (glands) in the groin, armpits, neck or elsewhere
- swelling, especially of the hands, ankles or feet
- diarrhoea
- dizziness or a spinning sensation (vertigo)
- low blood pressure (hypotension). You may feel dizzy or light-headed when standing up
- fast heart beat
- headache or feeling tired or weak
- changes to your vision and other eye problems such as infection, redness and inflammation or painful or gritty feeling in your eye
- bloodshot eyes (conjunctivitis) or swelling of your eye lids
- asthma may get worse

People who are also infected with the worm *Loa loa* may rarely have the following additional side effects:

- brain disorder (encephalopathy)
- neck or back pain
- red eye because of bleeding in the whites of your eyes
- being short of breath
- loss of control of your bladder or your bowels
- difficulty standing or walking
- mental status changes including agitation and difficulty speaking
- feeling drowsy or confused
- not responding to other people or going into a coma

People infected with the worms that cause **lymphatic filariasis** may have the following side effects:

- sweating or fever
- headache

- feeling unusually weak
- muscle, joint and general body pains
- loss of appetite, nausea
- pain in your stomach (abdominal and epigastric pain)
- cough or sore throat
- discomfort when breathing
- low blood pressure which may make you feel dizzy or lightheaded when you sit or stand up
- chills
- dizziness or a spinning sensation (vertigo)
- pain or discomfort in the testicles

People with intestinal strongyloidiasis may have the following side effects:

- dizziness
- itching
- diarrhoea, nausea (feeling sick)
- loss of appetite, stomach pain, vomiting, or constipation
- feeling sleepy
- a spinning sensation (vertigo)
- shaking or tremors
- decrease in the number of white blood cells (leucopenia)
- decrease in the number of red blood cells or the red blood pigment haemoglobin (anaemia)

Adult round worms killed by the medicine may be found in your stools.

People with scabies may have the following side effects:

- itching (pruritus) may get worse at the start of treatment. This does not usually last long.
- headache
- joint pain
- loss of appetite
- lack of energy
- discomfort in the abdomen (belly)
- rash
- dizziness

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [NT007 trade name]

Keep this medicine out of the sight and reach of children.

Do not store above 30°C. Avoid excursions above 30°C (*blister pack*).

Do not store above 30°C. Avoid excursions above 30°C. Keep the HDPE bottle tightly closed in order to protect from light (*Bottle pack*).

Do not use this medicine after the expiry date stated on label after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [NT007 trade name] contains

- The active ingredient is ivermectin.
- The other ingredients of [NT007 trade name] are microcrystalline cellulose, pregelatinized starch, citric acid, butylhydroxyanisole (E 320) and magnesium stearate.

What [NT007 trade name] looks like and contents of the pack

White uncoated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets are plain on both sides.

[NT007 trade name] is available in blister packs or bottle packs.

Blister pack

Aluminium-Aluminium blister cards containing either 1 or 10 tablets, each blister card is packed in an outer carton. Pack size: 1 and 10 tablets.

Bottle pack

White HDPE bottle with white polypropylene screw cap. The screw cap also contains a capsular desiccant. Pack size: 250 tablets.

Supplier and Manufacturer

Supplier

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For any information about this medicine, contact the local representative of the supplier.

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Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>